



30 AUG 2007

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD NJ 07090

In re Application of	:	
GOLLER, et al.	:	DECISION ON PETITION
Serial No.: 10/578,233	:	
PCT No.: PCT/US04/36477	:	UNDER 37 CFR 1.47(a)
Int. Filing Date: 03 November 2004	:	
Priority Date: 03 November 2003	:	
Atty Docket No.: TEVBNP 3.3-167	:	
For: SOFT STEROID COMPOSITIONS FOR	:	
USE IN DRY POWDER INHALERS	:	
	:	

This decision is in response to applicant's "Response to Notification of Missing Requirements under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) and Petition under 37 CFR 1.47(a)" filed 13 June 2007 to accept the application without the signatures of joint inventors, Qi Li, Katherine Salas, Anayo Ukeje and Ramesh Yanamandra. Applicant requests a five month extension of time, which is granted.

BACKGROUND

On 13 November 2006, a Notification of Missing Requirements was mailed to applicant indicating that an oath or declaration, in compliance with 37 CFR 1.497(a) and (b), and the surcharge for filing the oath or declaration after the thirty month period, was required.

On 13 June 2007, applicant filed a petition under 37 CFR 1.47(a) to accept the application without the signatures of joint inventors Qi Li, Katherine Salas, Michael Ukeje and Ramesh Yanamandra.

DISCUSSION

A petition under 37 CFR 1.47(a) must be accompanied by (1) the fee under 37 CFR 1.17(g), (2) factual proof that the missing joint inventor refuses to execute the application or cannot be reached after diligent effort, (3) a statement of the last known address of the missing inventor, and (4) an oath or declaration by each 37 CFR 1.47(a) applicant on his or her own behalf and on behalf of the non-signing joint inventor.

Items (1) and (3) above are satisfied.

Regarding item (2) above, Petitioner contends that Qi Li, Katherine Salas, Anayo Ukeje and Ramesh Yanamandra have refused to sign the application or are unavailable. In support of the petition, petitioner submits the affidavit of Samantha Claire Radley, Patent Administrator for Norton Healthcare Limited (assignee) regarding the nonsigning inventors' refusal or unavailability to sign the application papers.

With regard to inventor Qi Li, Ms. Radley states that on 3 August 2006, she "sent a bundle of documents consisting of a Declaration for Utility or Design Patent Application, a copy of the US patent application No. 10/578,233 and an Assignment" to Qi Li at his last known address. The documents were not returned. A copy of this letter and a copy of the receipt of delivery to Qi Li was not attached to the statement she provided.

Likewise a second letter from Ms. Radley to the inventor was sent on 1 March 2007, (attached as Exhibit SR1), which indicates that "the bundle of documents [a Declaration for Utility or Design Patent Application, a copy of the US patent application No. 10/578,233 and an Assignment]" were sent to Qi Li, which were returned as undeliverable. A copy of the envelope was not attached to the affidavit as stated therein. A review of the contents of the 01 March 2007 letter reveals the following: "Please find enclosed a declaration for use in the prosecution of the above United States patent application by Norton Healthcare Limited.". There is no mention that a complete copy of the application papers were included with the correspondence. Nor is there any documentary evidence that a complete copy of the application papers was presented to the nonsigning inventor in an itemized list of enclosures. Although Ms. Radley appears to indicate that a "copy of the application" papers was forwarded to the nonsigning inventor, the letter offered as Exhibit SR1 does not support such statement.

Ms. Radley further states that she made one email inquiry regarding the last known address of Qi Li with the above referenced U.S. law firm. Ms. Radley concludes that she cannot contact Qi Li at this time. However, Ms. Radley did not conduct a search of the Internet or contact the joint inventors in an attempt to locate the nonsigning inventor. Thus, further evidence of the diligent efforts made to locate nonsigning inventor Qi Li was not presented and is required. *Documentary evidence such as internet searches, certified mail return receipts, cover letters of instructions, telegrams, that support a finding that the nonsigning inventor could not be found or reached should be made part of the statement. The steps taken to locate the whereabouts of the nonsigning inventor should be included in the statement of facts.*

Ms. Radley provided similar affidavits for nonsigning inventors Katherine Salas, Anayo Ukeje and Ramesh Yanamandra. Her letters dated 01 March 2007 (attached as Exhibit SR1) do not provide documentary evidence that a complete copy of the application papers were mailed to the nonsigning inventors and do not support her statement that such papers were provided because the letters do not detail the contents or enclosures but mention only the declaration. Petitioner must provide the nonsigning inventors a complete copy of the application papers before a petition under 37 CFR 1.47(a) can be granted.

Moreover, postal receipts were not presented as evidence to demonstrate that the

inventors were presented with the application papers. The nonsigning inventors' silence cannot be construed as a refusal in the immediate circumstances as it is unclear whether they received the papers and whether the papers did in fact contain a complete copy of the application including an oath or declaration for execution.

Moreover, Ms. Radley's search for inventors Ukeje and Yanamandra through an internet phone book is insufficient as it is an incomplete search performed only for a telephone number and is restricted to a specific locale.

Refusal Of The Inventor To Sign The Application Papers

In cases where it is argued that the non-action of an inventor should be considered a refusal to cooperate, it is especially important to provide proof of delivery of the papers, as well as, a firsthand statement of the preparation and mailing of the papers.

Section 409.03(d) of the MPEP, Proof of Unavailability or Refusal, states, in part:

Where a refusal of the inventor to sign the application papers is alleged, the circumstances of the presentation of the application papers and of the refusal must be specified in a statement of facts by the person who presented the inventor with the application papers and/or to whom the refusal was made. Statements by a party not present when an oral refusal is made will not be accepted.

Proof that a *bona fide* attempt was made to present a copy of the application papers (specification, including claims, drawings, and oath or declaration) to the nonsigning inventor for signature, but the inventor refused to accept delivery of the papers or expressly stated that the application papers should not be sent, may be sufficient. When there is an express oral refusal, that fact along with the time and place of the refusal must be stated in the statement of facts. When there is an express written refusal, a copy of the document evidencing that refusal must be made part of the statement of facts. The document may be redacted to remove material not related to the inventor's reasons for refusal.

When it is concluded by the 37 CFR 1.47 applicant that a nonsigning inventor's conduct constitutes a refusal, all facts upon which that conclusion is based should be stated in the statement of facts in support of the petition or directly in the petition. If there is documentary evidence to support facts alleged in the petition or in any statement of facts, such evidence should be submitted. Whenever a nonsigning inventor gives a reason for refusing to sign the application oath or declaration, that reason should be stated in the petition.

As stated above, where a refusal of the inventor to sign the application papers is alleged, a statement of facts is needed from a person having first hand knowledge of the facts that a complete copy of the papers for this application (specification, claims, drawings and oath/declaration) were sent to the nonsigning inventors and when such papers were sent. In addition, copies of documentary evidence such as a certified mail return receipt, cover letter of

instruction, telegrams, etc., should be supplied with the declaration.

Inability To Find or Reach A Nonsigning Inventor

MPEP Section 409.03(d) also states: where inability to find or reach a nonsigning inventor "after diligent effort" is the reason for filing under 37 CFR 1.47, a statement of facts should be submitted that fully describes the exact facts which are relied on to establish that a diligent effort was made. The statement of facts must be signed, where at all possible, by a person having firsthand knowledge of the facts recited therein. Statements based on hearsay will not normally be accepted. Copies of documentary evidence such as internet searches, certified mail return receipts, cover letters of instructions, telegrams, that support a finding that the nonsigning inventor could not be found or reached should be made part of the statement. The steps taken to locate the whereabouts of the nonsigning inventor should be included in the statement of facts. It is important that the statement contain facts as opposed to conclusions. Petitioner has not yet demonstrated diligent efforts to find or reach the nonsigning inventors.

With respect to Item (4) above, petitioner filed multiple 2 page declarations. However, each declaration is incomplete, in that, each declaration does not identify all the inventors as listed on the published international application PCT/US04/36477. What is required is a newly executed declaration which identifies all the inventors and is in compliance with 37 CFR 1.497(a) and (b). Item (4) is not yet satisfied.

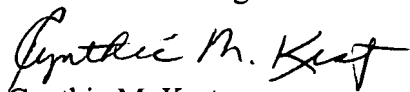
Applicant has not presented sufficient evidence to show that nonsigning inventors Qi Li, Katherine Salas, Anayo Ukeje and Ramesh Yanamandra were presented with and received a complete copy of the application papers including a declaration and that they refuse to sign or were unavailable to sign the application papers. In light of the above, Item (2) and (4) above are not yet satisfied and thus, it is inappropriate to grant applicant's petition under 37 CFR 1.47(a) at this time.

CONCLUSION

For the reasons stated above, applicant's petition under 37 CFR 1.47(a) is **DISMISSED**.

Any reconsideration on the merits of this petition must be filed within **TWO (2) MONTHS** from the mail date of this decision. Any reconsideration request should include a cover letter entitled "Renewed Petition Under 37 CFR 1.47(a)." Extensions of time may be obtained under 37 CFR 1.136(a).

Any further correspondence with respect to this matter should be directed to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.


Cynthia M. Kratz
Attorney-Advisor

Office of PCT Legal Administration

Tel: (571) 272-3286

Fax: (571) 273-0459